

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in this application.

1. (Previously Presented) Chemically stable lansoprazole comprising greater than 500 ppm and not more than about 3,000 ppm water, wherein lansoprazole is stable at a temperature of from 2°C to 8°C or at 25°C at a relative humidity of up to 60% for a period of up to about 6 months.
2. (Previously Presented) The chemically stable lansoprazole of claim 1, wherein the chemically stable lansoprazole comprises greater than about 600 ppm and not more than about 3,000 ppm water.
3. (Previously Presented) Chemically stable lansoprazole comprising greater than 200 ppm and not more than about 5,000 ppm alcohol, wherein lansoprazole is stable at a temperature of from 2°C to 8°C or at 25°C at a relative humidity of up to 60% for a period of up to about 6 months.
4. (Previously Presented) The chemically stable lansoprazole compound of claim 3, wherein the chemically stable lansoprazole comprises greater than about 300 ppm and not more than about 5,000 ppm alcohol.
5. (Previously Presented) Chemically stable lansoprazole comprising greater than 500 ppm and not more than about 3,000 ppm water, and greater than 200 ppm and not more than about 5,000 ppm alcohol, wherein lansoprazole is stable at a temperature of from 2°C to 8°C or at 25°C at a relative humidity of up to 60% for a period of up to about 6 months.
6. (Currently Amended) The chemically stable lansoprazole as in one of claims 1 to 5, further comprising less than about 0.1% (wt/wt) 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]sulfonyl]-1H-benzimidazole 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]sulfonyl]-1H-benzimidazole and less than about 0.1% (wt/wt) 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]thio]-1H-benzimidazole 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]thio]-1H-benzimidazole.
7. (Canceled).

8. (Withdrawn) A method of preparing a stable lansoprazole compound, comprising the steps of:

a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of an amine; and

b) isolating a stable lansoprazole compound,
wherein the stable lansoprazole compound comprises greater than 500 ppm and not more than about 3,000 ppm water.

9. (Withdrawn) The method of claim 8, wherein the stable lansoprazole compound comprises greater than about 600 ppm and not more than about 3,000 ppm water.

10. (Withdrawn) A method of preparing a stable lansoprazole compound, comprising the steps of:

a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of an amine; and

b) isolating a stable lansoprazole compound,
wherein the stable lansoprazole comprises greater than 200 ppm and not more than about 5,000 ppm alcohol.

11. (Withdrawn) The method of claim 10, wherein the stable lansoprazole compound comprises greater than about 300 ppm and not more than about 5,000 ppm alcohol.

12. (Withdrawn) A method of preparing a stable lansoprazole compound, comprising the steps of:

a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of an amine; and

b) isolating a stable lansoprazole compound,
wherein the stable lansoprazole compound comprises greater than 500 ppm and not more than about 3,000 water, and greater than 200 ppm, and not more than about 5,000 ppm alcohol.

13. (Withdrawn) The method as in any one of claims 8 to 12, wherein the organic solvent is at least one solvent selected from the group consisting of ethanol, methanol, n-propanol, i-propanol, dimethyl-carbonate, diethyl-carbonate, acetone, 2-butanone, dimethyl-formamide and tetrahydrofuran.

14. (Withdrawn) The method as in any one of claims 8 to 12, wherein the organic solvent is ethanol.

15. (Withdrawn) The method as in any one of claims 8 to 12, wherein the amine at least one compound selected from the group consisting of ammonia, ammonium hydroxide, diethylamine, triethylamine, methylamine, diethanolamine, and triethanolamine.

16. (Withdrawn) The method as in any one of claims 8 to 12, wherein the amine is ammonium hydroxide.

17. (Withdrawn) The method of claim 16, wherein the ammonium hydroxide is present at a mol/mol ratio to lansoprazole of about 7 to about 1.

18. (Withdrawn) The method of claim 17, wherein the ammonium hydroxide is present at a mol/mol ratio to lansoprazole of greater than about 1.

19. (Withdrawn) The method as in any one of claims 8 to 12, wherein the crystallizing step is achieved by acidifying the lansoprazole solution with an acid.

20. (Withdrawn) The method of claim 19, wherein the acid is at least one acid selected from the group consisting of acetic acid, formic acid, and hydrochloric acid.

21. (Withdrawn) The method of claim 19, wherein the acid is acetic acid.

22. (Withdrawn) The method as in any one of claims 8 to 12, wherein the stable lansoprazole compound further comprises less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% (wt/wt) sulfide derivative.

23. (Withdrawn) A method of purifying a lansoprazole compound, comprising the steps of:

a) crystallizing a lansoprazole from an organic solvent or a mixture of organic solvent and water in the presence of an amine; and

b) isolating a crystallized lansoprazole compound,
wherein the crystallized lansoprazole compound comprises less than about 0.1% (wt/wt) sulfone derivative and less than about 0.1% sulfide derivative (wt/wt) sulfide derivative.

24. (Withdrawn) The method of claim 23, after step a), further comprising the step of washing the crystallized lansoprazole compound in an acetone-water mixture.

25. (Withdrawn) The method of claim 24, wherein the acetone-water mixture is adjusted to a pH of about 8 to about 10.

26. (Withdrawn) The method of claim 24, wherein the acetone-water mixture is adjusted to a pH of about 9.

27. (Withdrawn) The method of claim 23, wherein the isolating step comprises drying the crystallized lansoprazole compound in the presence of a weakly basic gas.

28. (Withdrawn) The method of claim 27, wherein the weakly basic gas is ammonia or methylamine.

29. (Previously Presented) A pharmaceutical composition, comprising a chemically stable lansoprazole and a pharmaceutically acceptable excipient, wherein the chemically stable lansoprazole comprises greater than 500 ppm and not more than about 3,000 ppm water and is stable at a temperature of from 2°C to 8°C or at 25°C at a relative humidity of up to 60% for a period of up to about 6 months.

30. (Previously Presented) The pharmaceutical composition of claim 29, wherein the chemically stable lansoprazole comprises greater than about 600 ppm and not more than about 3,000 water.

31. (Previously Presented) A pharmaceutical composition comprising a chemically stable lansoprazole and a pharmaceutically acceptable excipient, wherein the chemically stable lansoprazole comprises greater than 200 ppm and not more than about 5,000 ppm alcohol and is stable at a temperature of from 2°C to 8°C or at 25°C at a relative humidity of up to 60% for a period of up to about 6 months.

32. (Previously Presented) The pharmaceutical composition of claim 31, wherein the chemically stable lansoprazole comprises greater than about 300 ppm and not more than about 5,000 ppm alcohol.

33. (Previously Presented) A pharmaceutical composition comprising a chemically stable lansoprazole and a pharmaceutically acceptable excipient, wherein the chemically stable lansoprazole comprises greater than 500 ppm and not more than about 3,000 ppm water and greater than 200 ppm and not more than about 5,000 ppm alcohol and is stable at a temperature of from 2°C to 8°C or at 25°C at a relative humidity of up to 60% for a period of up to about 6 months.

34. (Currently Amended) The pharmaceutical composition as in any one of claims 29 to 33, wherein the chemically stable lansoprazole comprises less than about 0.1% (wt/wt) ~~2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]sulfonyl]-1H benzimidazole~~ 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]sulfonyl]-1H benzimidazole and less than about 0.1% (wt/wt) ~~2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]thio]-1H benzimidazole~~ 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]thio]-1H benzimidazole.

35. (Original) The pharmaceutical composition as in any one of claims 29 to 33, wherein the pharmaceutical composition is in a dosage form selected from the group consisting of tablets, powders, capsules, suppositories, sachets, troches, lozenges, liquid syrups, suspensions and elixirs.

36. (Original) The pharmaceutical composition as in any one of claims 29 to 33, wherein the pharmaceutical composition is a tablet.

37. (Previously Presented) The pharmaceutical composition as in any one of claims 29 to 33, wherein the pharmaceutical composition comprises chemically stable lansoprazole in a dosage level of from about 50 to about 300 mg.

38. (Previously Presented) The pharmaceutical composition as in any one of claims 29 to 33, wherein the pharmaceutical composition comprises chemically stable lansoprazole in a dosage level of about 200 mg.

39. (Currently Amended) The chemically stable lansoprazole as in claim 6, comprising less than about 0.05% (wt/wt) ~~2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]sulfonyl]-1H benzimidazole~~ 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]sulfonyl]-1H benzimidazole and less than about 0.05% (wt/wt) ~~2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]thio]-1H benzimidazole~~ 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]thio]-1H benzimidazole.

40. (Currently Amended) The pharmaceutical composition as in claim 34, wherein the chemically stable lansoprazole comprises less than about 0.05% (wt/wt) ~~2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]sulfonyl]-1H benzimidazole~~ 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]sulfonyl]-1H benzimidazole and less than about 0.05% (wt/wt) ~~2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]thio]-1H benzimidazole~~ 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]thio]-1H benzimidazole.